

(c) a manifold providing an interface between said multi-lumen main body portion and said plurality of extension tubes,

wherein:

(d) said multi-lumen main body portion comprises:

- (i) at least one lumen for holding and supporting fiber optic filaments;
- (ii) at least one lumen for receiving thermal element connectors;
- (iii) at least one lumen for receiving a device for temperature measurement;
- (iv) at least one lumen associated with a balloon mounted at the distal end of said multi-lumen main body portion for assisting in placement of said multi-lumen main body portion in a patient; and
- (v) a fiber optic apparatus associated with the catheter including optical filaments disposed in said at least one lumen for holding and supporting fiber optic filaments, said fiber optic filaments extending the working length of said multi-lumen main body portion and into a fiber optic coupler associated with the catheter;

(e) a temperature measurement apparatus is mounted at the distal end of said multi-lumen main body portion;

(f) wiring extends the working length of said multi-lumen main body portion and into a housing associated with said multi-lumen main body portion;

(g) an external thermal element is placed on said multi-lumen main body portion near the distal end of said multi-lumen main body portion;

(h) connectors extend from said external thermal element along the working length of said multi-lumen main body portion to be connected to a thermal element housing at the proximal end of said multi-lumen main body portion;

(i) said external thermal element is operative with an external apparatus to provide a measurement of continuous cardiac output; and

(j) said fiber optic apparatus is cooperative with external apparatus for providing a measurement of mixed venous oxygen saturation.

## II. 37 CFR 1.604(a)(2)

The other application is application S.N. 914,279 (hereinafter referred to as "the '279 application"), filed on July 16, 1992 and/or any continuation or divisional thereof. The probable inventors are David A. Gallup, Timothy J. Hughes, and John Sperinde. The probable assignee is Abbott Laboratories. The '279 application is identified as the priority application in PCT application WO94/02066.

Claims 1-17 in the published PCT application would correspond to the proposed count. If similar claims are

pending in the '279 application, they should be designated as corresponding to the count.

III. Claims Presented for Interference

Please add Claims 45-58 as follows:

Sub C17

--45. A multi-lumen, multi-purpose cardiac catheter comprising:

- (a) a multi-lumen main body portion;
- (b) a plurality of extension tubes, each one of said plurality of extension tubes being connected to a respective lumen of said multi-lumen main body portion; and
- (c) a manifold providing an interface between said multi-lumen main body portion and said plurality of extension tubes, wherein:
  - (d) said multi-lumen main body portion comprises:
    - (i) at least one lumen for holding and supporting fiber optic filaments;
    - (ii) at least one lumen for receiving thermal element connectors;
    - (iii) at least one lumen for receiving a device for temperature measurement;
    - (iv) at least one lumen associated with a balloon mounted at the distal end of said multi-lumen main body portion for assisting in placement of said multi-lumen main body portion in a patient; and

B1

(v) a fiber optic apparatus associated with the catheter including optical filaments disposed in said at least one lumen for holding and supporting fiber optic filaments, said fiber optic filaments extending the working length of said multi-lumen main body portion and into a fiber optic coupler associated with the catheter;

(e) a temperature measurement apparatus is mounted at the distal end of said multi-lumen main body portion;

(f) wiring extends the working length of said multi-lumen main body portion and into a housing associated with said multi-lumen main body portion;

B1 (g) an external thermal element is placed on said multi-lumen main body portion near the distal end of said multi-lumen main body portion;

(h) connectors extend from said external thermal element along the working length of said multi-lumen main body portion to be connected to a thermal element housing at the proximal end of said multi-lumen main body portion;

(i) said external thermal element is operative with an external apparatus to provide a measurement of continuous cardiac output; and

(j) said fiber optic apparatus is cooperative with external apparatus for providing a measurement of mixed venous oxygen saturation.

46. The multi-lumen, multi-purpose cardiac catheter of claim 45 wherein:

(a) said multi-lumen main body portion includes a necked-down portion;

(b) said necked-down portion is disposed near the distal end of said multi-lumen main body portion; and

(c) said external thermal element is disposed in said necked-down portion.

47. The multi-lumen, multi-purpose cardiac catheter of claim 46, wherein:

(a) said necked-down portion is 5-10 centimeters in length and

(b) said necked-down portion is disposed approximately 14-15 centimeters from the distal end of said multi-lumen main body portion.

48. The multi-lumen, multi-purpose cardiac catheter of claim 46 wherein said external thermal element comprises a heater coil wound about said necked-down portion.

Sub C2 49. The multi-lumen, multi-purpose cardiac catheter of claim 48, wherein said temperature measurement apparatus comprises a thermistor which is adjacent the distal end of said heater coil.

50. The multi-lumen, multi-purpose cardiac catheter of claim 48, wherein said heater coil comprises windings pitched at a center-to-center spacing sufficient to separate adjacent coils.

51. The multi-lumen, multi-purpose cardiac catheter of claim 48, wherein said heater coil is surrounded by a thin outer sheath to prevent said external thermal element from directly contacting the patient's blood.

Subc3 >

52. The multi-lumen, multi-purpose cardiac catheter of claim 51, wherein said heater coil and said thin outer sheath generally approximate the diameter of said multi-lumen main body portion, thereby facilitating a smooth insertion of said multi-lumen main body portion into the body of the patient.

53. The multi-lumen, multi-purpose cardiac catheter of claim 45, wherein:

(a) at least one lumen of said multi-lumen main body portion is an injectate lumen and

(b) said injectate lumen is dedicated to proximal fluid infusion, thereby enabling injection of an injectate fluid into the blood stream of the patient to obtain thermal dilution readings at said thermistor to provide values for use in calculating intermittent cardiac output values.

54. The multi-lumen, multi-purpose cardiac catheter of claim 45, wherein said external thermal element comprises a thin film member spirally wound about said multi-lumen main body portion near the distal end of said multi-lumen main body portion.

55. The multi-lumen, multi-purpose cardiac catheter of claim 45, wherein:

(a) said external thermal element comprises a heating filament printed on a substrate as a sandwich and

B1

(b) said substrate is a thin material that is capable of being incorporated into a filament material that is flexible and has the ability to bond with an adhesive.

56. The multi-lumen, multi-purpose cardiac catheter of claim 45, wherein said external thermal element comprises a layer of material with high thermal conductivity to help create a more uniform surface temperature.

57. A multi-lumen, multi-purpose cardiac catheter comprising:

- (a) a multi-lumen main body portion;
- (b) a plurality of extension tubes, each one of said plurality of extension tubes being connected to a respective lumen of said multi-lumen main body portion; and
- (c) a manifold providing an interface between said multi-lumen main body portion and said plurality of extension tubes,

wherein:

(d) said multi-lumen main body portion comprises:

- (i) at least one lumen for holding and supporting fiber optic filaments;
- (ii) at least one lumen for receiving thermal element connectors;
- (iii) at least one lumen for receiving a device for temperature measurement;
- (iv) at least one lumen associated with a balloon mounted at the distal end of said multi-lumen main body portion for assisting in placement

of said multi-lumen main body portion in a patient; and

- (v) a fiber optic apparatus associated with the catheter including optical filaments disposed in said at least one lumen for holding and supporting fiber optic filaments, said fiber optic filaments extending the working length of said multi-lumen main body portion and into a fiber optic coupler associated with the catheter;

(e) a temperature measurement apparatus is mounted at the distal end of said multi-lumen main body portion;

B' (f) wiring extends the working length of said multi-lumen main body portion and into a housing associated with said multi-lumen main body portion;

(g) a necked-down portion of said multi-lumen main body portion is disposed near the distal end of said multi-lumen main body portion;

(h) an external thermal element is placed on said necked-down portion;

(i) connectors extend from said external thermal element along the working length of said multi-lumen main body portion to be connected to a thermal element housing at the proximal end of said multi-lumen main body portion;

(j) said external thermal element is operative with an external apparatus to provide a measurement of continuous cardiac output; and



(k) said fiber optic apparatus is cooperative with external apparatus for providing a measurement of mixed venous oxygen saturation.

58. A multi-lumen, multi-purpose cardiac catheter comprising:

- (a) a multi-lumen main body portion;
  - (b) a plurality of extension tubes, each one of said plurality of extension tubes being connected to a respective lumen of said multi-lumen main body portion; and
  - (c) a manifold providing an interface between said main body portion and said plurality of extension tubes,
- wherein:

(d) said multi-lumen main body portion comprises:

- (i) at least one lumen for holding and supporting fiber optic filaments;
- (ii) at least one lumen for receiving thermal element connectors;
- (iii) at least one lumen for receiving a device for temperature measurement;
- (iv) at least one lumen associated with a balloon mounted at the distal end of said multi-lumen main body portion for assisting in placement of said multi-lumen main body portion in a patient; and
- (v) a fiber optic apparatus associated with the catheter including optical filaments disposed in said at least one lumen for holding and

B1

supporting fiber optic filaments, said fiber optic filament extending the working length of said multi-lumen main body portion and into a fiber optic coupler associated with the catheter;

(e) a temperature measurement apparatus is mounted at the distal end of said multi-lumen main body portion;

(f) wiring extends the working length of said multi-lumen main body portion and into a housing associated with said multi-lumen main body portion;

(g) a necked-down portion of said multi-lumen main body portion is disposed near the distal end of said multi-lumen main body portion;

(h) an external thermal element is placed on said necked-down portion;

(i) connectors extend from said external thermal element along the working length of said multi-lumen main body portion to be connected to a thermal element housing at the proximal end of said multi-lumen main body portion;

(j) at least one lumen of said multi-lumen main body portion comprises an injectate lumen;

(k) said injectate lumen is dedicated to proximal fluid infusion;

(l) said external thermal element is operative with an external apparatus to provide a measurement of continuous cardiac output;

(m) said fiber optic apparatus is cooperative with external apparatus for providing a measurement of mixed venous oxygen saturation; and

B) (n) said injectate lumen enables injection of an injectate fluid into the blood stream of the patient to obtain thermal dilution readings at said temperature measurement apparatus to provide values for use in calculating intermittent cardiac output values. ✓

IV. 37 CFR 1.604(a)(3)

Claims 45-58 are modeled after claims 1-17 in the published PCT application. If similar claims are pending in the '279 application (or any continuation thereof), an interference should be declared between that application and claims 45-58 in this application.

V. Application of Claims 67-83 to Applicants' Disclosure

The foregoing claims may be applied to applicants' disclosure as follows:

45. A multi-lumen, multi-purpose cardiac catheter comprising:

Passim.

a) a multi-lumen main body portion;

The flexible catheter body portion 100.

(b) a plurality of extension tubes, each one of said plurality of extension tubes being connected to a respective lumen of said multi-lumen main body portion; and

Page 16 line 35 - page 17 line 4.

(c) a manifold providing an interface between said

The catheter body junction 106.

multi-lumen main body portion  
and said plurality of  
extension tubes,

wherein:

(d) said multi-lumen  
main body portion comprises:

(i) at least one  
lumen for holding and  
supporting fiber optic  
filaments;

Page 24 line 36 - page 25 line  
1.

(ii) at least one  
lumen for receiving thermal  
element connectors;

See Figure 1 and page 16 line  
35 - page 17 line 4. The  
heater extension tube is  
received in one of the lumens.

(iii) at least one  
lumen for receiving a device  
for temperature measurement;

See Figure 1 and page 16 line  
35 - page 17 line 4. The  
thermistor or thermocouple  
extension tube is received in  
one of the lumens.

(iv) at least one  
lumen associated with a  
balloon mounted at the distal  
end of said multi-lumen main  
body portion for assisting in  
placement of said multi-lumen  
main body portion in a  
patient; and

See Figure 1 and page 16 line  
35 - page 17 line 4. The  
balloon inflation extension  
tube is received in one of the  
lumens.

(v) a fiber optic  
apparatus associated with the  
catheter including optical  
filaments disposed in said at  
least one lumen for holding  
and supporting fiber optic  
filaments, said fiber optic  
filaments extending the  
working length of said multi-  
lumen main body portion and  
into a fiber optic coupler  
associated with the catheter;

Page 24 line 36 - page 25 line  
1.

(e) a temperature  
measurement apparatus is  
mounted at the distal end of  
said multi-lumen main body  
portion;

The thermistor or thermocouple  
104.

(f) wiring extends the working length of said multi-lumen main body portion and into a housing associated with said multi-lumen main body portion;

See Figure 1 and page 17 line 34 - page 18 line 14.

(g) an external thermal element is placed on said multi-lumen main body portion near the distal end of said multi-lumen main body portion;

The heating filament 400.

(h) connectors extend from said external thermal element along the working length of said multi-lumen main body portion to be connected to a thermal element housing at the proximal end of said multi-lumen main body portion;

The heater filament 400 is connected to the heater connector 116.

(i) said external thermal element is operative with an external apparatus to provide a measurement of continuous cardiac output; and

The cardiac output computer is the external apparatus.

(j) said fiber optic apparatus is cooperative with external apparatus for providing a measurement of mixed venous oxygen saturation.

Page 24 line 26 - page 25 line 1.

46. The multi-lumen, multi-purpose cardiac catheter of claim 45 wherein:

(a) said multi-lumen main body portion includes a necked-down portion;

Page 20 lines 20-31.

(b) said necked-down portion is disposed near the distal end of said multi-lumen main body portion; and

Page 18 lines 22-26.

(c) said external thermal element is disposed in said necked-down portion.

See Figure 4(b).

47. The multi-lumen, multi-purpose cardiac catheter of claim 46, wherein:

(a) said necked-down portion is 5-10 centimeters in length and

Page 18 lines 22-24 and page 22 lines 3-7.

(b) said necked-down portion is disposed approximately 14-15 centimeters from the distal end of said multi-lumen main body portion.

Page 18 lines 22-26 and page 22 lines 3-7.

48. The multi-lumen, multi-purpose cardiac catheter of claim 46 wherein said external thermal element comprises a heater coil wound about said necked-down portion.

Page 18 lines 15-29.

49. The multi-lumen, multi-purpose cardiac catheter of claim 48, wherein said temperature measurement apparatus comprises a thermistor which is adjacent the distal end of said heater coil.

Page 16 lines 21-24.

50. The multi-lumen, multi-purpose cardiac catheter of claim 48, wherein said heater coil comprises windings pitched at a center-to-center spacing sufficient to separate adjacent coils.

See Figure 4(b) and page 18 lines 18-20.

51. The multi-lumen, multi-purpose cardiac catheter of claim 48, wherein said heater coil is surrounded by a thin outer sheath to prevent said external thermal element from directly contacting the patient's blood.

Page 18 lines 26-29.

52. The multi-lumen, multi-purpose cardiac catheter of claim 51, wherein said heater coil and said thin outer sheath generally approximate the diameter of said multi-lumen main body portion, thereby facilitating a smooth insertion of said multi-lumen main body portion into the body of the patient.

See Figure 4(b) and page 20 lines 20-31.

53. The multi-lumen, multi-purpose cardiac catheter of claim 45, wherein:

(a) at least one lumen of said multi-lumen main body portion is an injectate lumen and

Page 16 line 37 - page 17 line 1 and page 24 lines 34-35.

(b) said injectate lumen is dedicated to proximal fluid infusion, thereby enabling injection of an injectate fluid into the blood stream of the patient to obtain thermal dilution readings at said thermistor to provide values for use in calculating intermittent cardiac output values.

Passim, particularly page 24 lines 34-35.

54. The multi-lumen, multi-purpose cardiac catheter of claim 45, wherein said external thermal element comprises a thin film member spirally wound about said multi-lumen main body portion near the distal end of said multi-lumen main body portion.

Page 18 lines 15-29.

55. The multi-lumen, multi-purpose cardiac catheter of claim 45, wherein:

(a) said external thermal element comprises a

Page 18 lines 30-31.

heating filament printed on a substrate as a sandwich and

(b) said substrate is a thin material that is capable of being incorporated into a filament material that is flexible and has the ability to bond with an adhesive.

Page 18 lines 31-34.

56. The multi-lumen, multi-purpose cardiac catheter of claim 45, wherein said external thermal element comprises a layer of material with high thermal conductivity to help create a more uniform surface temperature.

Page 18 line 37 - page 19 line 1.

57. A multi-lumen, multi-purpose cardiac catheter comprising:

Passim.

(a) a multi-lumen main body portion;

The flexible catheter body portion 100.

(b) a plurality of extension tubes, each one of said plurality of extension tubes being connected to a respective lumen of said multi-lumen main body portion; and

Page 16 line 35 - page 17 line 4.

(c) a manifold providing an interface between said multi-lumen main body portion and said plurality of extension tubes,

The catheter body junction 106.

wherein:

(d) said multi-lumen main body portion comprises:

(i) at least one lumen for holding and supporting fiber optic filaments;

Page 24 line 36 - page 25 line 1.

(ii) at least one

See Figure 1 and page 16 line 35 - page 17 line 4. The



lumen for receiving thermal element connectors;

(iii) at least one lumen for receiving a device for temperature measurement;

(iv) at least one lumen associated with a balloon mounted at the distal end of said multi-lumen main body portion for assisting in placement of said multi-lumen main body portion in a patient; and

(v) a fiber optic apparatus associated with the catheter including optical filaments disposed in said at least one lumen for holding and supporting fiber optic filaments, said fiber optic filaments extending the working length of said multi-lumen main body portion and into a fiber optic coupler associated with the catheter;

(e) a temperature measurement apparatus is mounted at the distal end of said multi-lumen main body portion;

(f) wiring extends the working length of said multi-lumen main body portion and into a housing associated with said multi-lumen main body portion;

(g) a necked-down portion of said multi-lumen main body portion is disposed near the distal end of said multi-lumen main body portion;

(h) an external thermal element is placed on said necked-down portion;

heater extension tube is received in one of the lumens.

See Figure 1 and page 16 line 35 - page 17 line 4. The thermistor or thermocouple extension tube is received in one of the lumens.

See Figure 1 and page 16 line 35 - page 17 line 4. The balloon inflation extension tube is received in one of the lumens.

Page 24 line 36 - page 25 line 1.

The thermistor or thermocouple 104.

See Figure 1 and page 17 line 34 - page 18 line 14.

Page 20 lines 20-31 and page 18 lines 22-26.

See Figure 4(b).

(i) connectors extend from said external thermal element along the working length of said multi-lumen main body portion to be connected to a thermal element housing at the proximal end of said multi-lumen main body portion;

(j) said external thermal element is operative with an external apparatus to provide a measurement of continuous cardiac output; and

(k) said fiber optic apparatus is cooperative with external apparatus for providing a measurement of mixed venous oxygen saturation.

58. A multi-lumen, multi-purpose cardiac catheter comprising:

(a) a multi-lumen main body portion;

(b) a plurality of extension tubes, each one of said plurality of extension tubes being connected to a respective lumen of said multi-lumen main body portion; and

(c) a manifold providing an interface between said main body portion and said plurality of extension tubes,

wherein:

(d) said multi-lumen main body portion comprises:

(i) at least one lumen for holding and supporting fiber optic filaments;

The heating filament 400 is connected to the heater connector 116.

The cardiac output computer is the external apparatus.

Page 24 line 26 - page 25 line 1.

Passim.

The flexible catheter body portion 100.

Page 16 line 35 - page 17 line 4.

The catheter body junction 106.

Page 24 line 36 - page 25 line 1.

(ii) at least one lumen for receiving thermal element connectors;

(iii) at least one lumen for receiving a device for temperature measurement;

(iv) at least one lumen associated with a balloon mounted at the distal end of said multi-lumen main body portion for assisting in placement of said multi-lumen main body portion in a patient; and

(v) a fiber optic apparatus associated with the catheter including optical filaments disposed in said at least one lumen for holding and supporting fiber optic filaments, said fiber optic filaments extending the working length of said multi-lumen main body portion and into a fiber optic coupler associated with the catheter;

(e) a temperature measurement apparatus is mounted at the distal end of said multi-lumen main body portion;

(f) wiring extends the working length of said multi-lumen main body portion and into a housing associated with said multi-lumen main body portion;

(g) a necked-down portion of said multi-lumen main body portion is disposed near the distal end of said multi-lumen main body portion;

See Figure 1 and page 16 line 35 - page 17 line 4. The heater extension tube is received in one of the lumens.

See Figure 1 and page 16 line 35 - page 17 line 4. The thermistor or thermocouple extension tube is received in one of the lumens.

See Figure 1 and page 16 line 35 - page 17 line 4. The balloon inflation extension tube is received in one of the lumens.

Page 24 line 36 - page 25 line 1.

The thermistor or thermocouple 104.

See Figure 1 and page 17 line 34 - page 18 line 14.

Page 20 lines 20-31 and page 18 lines 22-26.

(h) an external thermal element is placed on said necked-down portion;

See Figure 4(b).

(i) connectors extend from said external thermal element along the working length of said multi-lumen main body portion to be connected to a thermal element housing at the proximal end of said multi-lumen main body portion;

The heating filament 400 is connected to the heater connector 116.

(j) at least one lumen of said multi-lumen main body portion comprises an injectate lumen;

Page 16 line 37 - page 17 line 1 and page 24 lines 34-35.

(k) said injectate lumen is dedicated to proximal fluid infusion;

Page 24 lines 34-35.

(l) said external thermal element is operative with an external apparatus to provide a measurement of continuous cardiac output;

The cardiac output computer is the external apparatus.

(m) said fiber optic apparatus is cooperative with external apparatus for providing a measurement of mixed venous oxygen saturation; and

Page 24 line 26 - page 25 line 1.

(n) said injectate lumen enables injection of an injectate fluid into the blood stream of the patient to obtain thermal dilution readings at said temperature measurement apparatus to provide values for use in calculating intermittent cardiac output values.

Passim.

VI. The Form PTO-850

A draft Form PTO-850 is submitted herewith for the convenience of the examiner.

Respectfully submitted,



Richard A. Neifeld  
Registration No. 35,299

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.  
Crystal Square Five - Fourth Floor  
1755 Jefferson Davis Highway  
Arlington, Virginia 22202  
(703) 413-3000

Of Counsel

Richard Neifeld, Ph.D.  
Registration No. 35,299  
OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.  
Crystal Square Five - Fourth Floor  
1755 Jefferson Davis Highway  
Arlington, Virginia 22202  
(703) 413-3000

Bruce M. Canter, Esq.  
Registration No. 34,792  
BAXTER HEALTHCARE CORPORATION  
P.O. Box 15210  
Irvine, CA 92713-5210  
(714) 440-5345